

REMARKS

In the Office Action dated May 11, 2007, Claims 1-3 were rejected under 35 U.S.C. §103(a) as being unpatentable over an article by van der Weide et al. The Examiner stated that the van der Weide et al. article discloses a method for digital subtraction angiography that exploits the 3D vasculature information which the Examiner characterized as being “inherent” in computed tomographic angiography scans. The Examiner acknowledged that the van der Weide et al. article does explicitly disclose generating a 2D x-ray image from the 3D volumetric dataset obtained from a CTA scan, but stated that the advantage of using such a 3D volumetric dataset obtained from the CTA scan is “implicit” in the method disclosed in the van der Weide et al. article, and therefore the Examiner stated this “would have been obvious and necessitated.”

Applicant respectfully disagrees with each of the above statements made by the Examiner, as well as the conclusions based thereon.

Applicant's disagreement with the Examiner's statements and conclusions is primarily due to the fact, which is well known to those of ordinary skill in the field of medical imaging, that computed tomography angiography (CTA) is, by definition, an imaging modality, as is any angiography technique, that makes use of the administration of a contrast agent to the examination subject in order to enrich the vessels of interest so that they will be easily visible in the resulting angiographic image. If anything is “inherent” in CTA, it is that it is impossible to obtain CTA data without the use of a contrast agent. As noted above, this is inherent in the very definition of “angiography,” and is clear from the van der Weide et al. article itself, because all of the actual or simulated images that are reproduced in that article are

clearly angiography images that show the presence of contrast agent in the vessels of interest, and the use of a contrast agent is explicitly noted in the van der Weide et al. article at page 839, in the first paragraph of the left column of text.

This is in direct contrast to the explicit language of claim 1 of the present application, which requires that 3D volume dataset be provided that has been obtained from a computed tomography scan of a body region containing structures *without enrichment of the structures with a contrast agent* (emphasis added).

When discussing CTA data, one cannot simply “imagine” CTA data without the presence of a contrast agent, since the presence of a contrast agent is one of the defining features of any type of angiographic data, including CTA data. More to the point, the Examiner is not permitted to assert that a person of ordinary skill in the field of medical imaging would ignore the necessity of the use of a contrast agent for acquiring CTA data without the Examiner providing extensive substantiating evidence for such an assumption. Although the Examiner cited the decision in *Graham v. John Deere Co.* in the Office Action, the Examiner clearly did not follow the requirements of that decision, because the Examiner did not “resolve the level of ordinary skill in the pertinent art” and did not “evaluate evidence of secondary considerations for indicating obviousness or non-obviousness.” If the Examiner had “resolved the level of ordinary skill in the pertinent art,” the Examiner would inescapably have realized that those of ordinary skill in the field of medical imaging have a clear and unambiguous understanding of what is encompassed by CTA, and CTA data, and this would have included the aforementioned necessity of the use of a contrast agent, in direct contradiction to the language of independent claim 1.

Moreover, if the Examiner had evaluated “evidence of secondary considerations for indicating obviousness or non-obviousness,” the Examiner would have recognized that despite making extensive use of CTA data in the context of 2D angiography (but for a completely different purpose from the subject matter of the claims of the present application, as discussed in more detail below), it never occurred to the authors of the van der Weide et al. article to make use of 3D volumetric CT data obtained *without* the use of a contrast agent. This is evidence of other persons of ordinary skill in the same technology working on solutions to similar problems, but completely failing to have the insight that the present inventors have had to extract a 2D x-ray image from a 3D volumetric dataset obtained without the use of a contrast agent, i.e., a non-angiographic 3D volumetric dataset. If the Examiner’s characterization of the disclosure of the van der Weide et al. article is accepted (contrary to Applicant’s position), then van der Weide et al. had information “at their fingertips” allegedly pointing them in the direction of the subject matter of the present claims, but failed to recognize that information or have the insight that the present Applicants have had, namely to extract a 2D x-ray image from a 3D volumetric data set obtained *without* the use of a contrast agent. Surely, if not using a contrast agent to obtain the 3D volumetric dataset were as obvious as the Examiner contends, then at least in regard to the simulated images, which are discussed in detail in the van der Weide et al. reference, there would have been a mention of the “option” of not having to go to the trouble to simulate the presence of a contrast agent. In the absence of any mention whatsoever of the possibility of using any type of 3D CT volumetric dataset *without* administering a contrast agent, it is clear that the authors in the van der Weide et al. article did, in fact, consider the

use of, and the presence of, a contrast agent to be necessitated in the technique disclosed in that article. This is also apparent from the discussion in the van der Weide et al. article of the problem that the technique disclosed therein is intended to overcome.

As described in the section labeled "Introduction" in the van der Weide et al. article, CTA has a high sensitivity rate for detecting cerebral aneurisms, but small aneurisms are sometimes missed or falsely detected using CTA. For this purpose, radiologists commonly do not rely exclusively on CTA, but use it in a complimentary manner with conventional digital subtraction angiography (DSA). A disadvantage of DSA, however, is that accurate visualization of the shape of the aneurism is dependent on the projection angle from which the DSA data are acquired. For example, an aneurism that projects from only one side of a vessel may not be clearly visible from a projection angle that is at the same side of the vessel from which the aneurism projects. Such an aneurism may be clearly visible, however, in a projection at 90° from the aforementioned projection.

In order to overcome these problems and to be able to combine CTA and DSA, van der Weide et al. propose acquiring CTA data in order to obtain a CTA 3D volume dataset of the vasculature in question, including the aneurism and its "neck" and its parent vessel. The neck is then isolated and the size and shape of the neck are determined. One or more optical projection angles are then calculated that will cause the neck to be shown separated from the aneurism and the blood vessels. DSA data are then acquired at the calculated optimal projection angles, in order to permit a precise determination of the diameter of the aneurism neck.

Since it is a problem involving vasculature, and in particular vasculature aneurisms, that is being addressed by van der Weide et al., it is essential in the van der Weide et al. procedure that CTA as well as DSA be employed, with the administration of a contrast agent for obtaining the CTA data being essential for achieving the goal of being able to identify the optimal projection angles for the subsequently-acquired DSA data. The method disclosed in the van der Weide et al. article does not include the calculation of a 2D x-ray image out of the CTA data, because there would be no advantage to doing so in the method disclosed in that article. As noted above, and as acknowledged in the van der Weide et al. article, the resolution of CTA images, particularly for small aneurisms, is not good enough (page 831, right column, third paragraph). Therefore, it would not make sense to use CTA data, which is known to be insufficient for detecting the types of aneurisms that van der Weide et al. are interested in detecting, for the purpose of calculating a 2D x-ray image from the CTA data. Van der Weide et al. (logically) used the information contained in the CTA data exclusively to determine optimal projection angles for the subsequent DSA examination, in order to provide the appropriate resolution for detecting small aneurisms.

Applicants therefore respectfully submit that the Examiner has not provided adequate substantiation (and in fact has provided no substantiation whatsoever) for the Examiner's conclusion regarding the alleged obviousness of not using CTA data in the method disclosed in van der Weide et al. The subject matter of claim 1, therefore, would not have been obvious to a person of ordinary skill in the field of medical imaging or medical angiography, under the provisions of 35 U.S.C. §103(a).


Dependent claims 2 and 3 add further steps to the non-obvious method of claim 1, and would not have been obvious to a person of ordinary skill in the field of medical imaging based on the teachings of van der Weide et al. for the same reasons discussed above in connection with claim 1.

An editorial change has been made in claim 1 to provide antecedent basis for the term "second 2D x-ray image." As should be apparent from the above discussion, this change has not been made for the purpose of distinguishing claim 1 over the teachings of the van der Weide et al. article, or any other prior art of record.

Early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

 (Reg. 28,982)

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